

LETTER OF ANNOUNCEMENT
EMVS Known Issues

22nd February 2019

Dear all,

EMVO is contacting you to provide an update on the current status of the EMVS together with the actions which have been, and will be, taken to mitigate Known Issues. Today's communication follows the conclusions from yesterday's FMD implementation workshop.

Known Issues

1. Missing Call-backs

EMVO now believe that the majority of issues related to Missing Call-backs have been resolved. The main issue last week related to Multi-Market Pack Synchronisation which prevented responses from being sent by some NMVS's due to the extreme system load has now been resolved.

Further remaining known defects have been identified; and affect 0.75% of existing Product Master Data records. There is no remedial action that can be undertaken by an ONP. This defect results in failures in processing Product Master Data and Product Pack Data. EMVO is working to remove these defects by means of software code change within the Hub. **One fix will be in place, at the latest, by 28th February and the second by 6th March.** The first fix will be to cleanse the relevant data, with the second fix being to resolve the underlying issue. All affected OBPs have, by this morning, been provided with this information and given the relevant Product Codes.

EMVO will also continue to proactively monitor the performance of call-backs to product pack data uploads to confirm defect resolution.

2. Re-upload of Pack Data (batches)

As was stated in EMVO's communication on Tuesday 19th February, during last week and the weekend, OBPs were experiencing that they did not receive either a 'Distributed' or a 'Distribution Failed' call-back message. They are therefore re-uploading the data and may then receive a 'Distribution Failed' call-back, including a series of #A32 notifications, 'Duplicate serial number'.

To that end, EMVO provided the following advice:

If you receive the 'Distribution Failed' call-back where the underlying error payload indicates that all serial numbers in the transaction received the #A32 notification; then there has been, by definition, an earlier successful distribution. This guidance only applies in this one specific instance.

EMVO can inform you that this topic will also be escalated to EMVO's Technical Advisory Group, as per the request from OBPs at yesterday's FMD implementation workshop. EMVO will discuss the proposal to change this operation to return 'Distributed' instead of 'Distribution Failure' and retain the list of duplicate serial numbers.

3. Alert propagation and reconfiguration

Further to the discussion at yesterday's FMD workshop, the reconfiguration of the alert propagation will be escalated to EMVO's Technical Advisory Group. The Group will be requested to discuss this topic and provide guidance on how to reconfigure the propagation. However, the plan is to deactivate the propagation of A17 alerts. This change will be deployed in PRD on Tuesday 26th February.

4. Expiry Date issues

In the previous week, many issues have been noted with expiry date mis-match. After investigating this issue, one major root cause has been identified as being linked to end user system implementation. EMVO will orchestrate the response to this issue, as this will have to be addressed individually by end-user system providers, and will inform the end-user system providers of the issue and the effect caused with an aim to provide a rapid resolution. EMVO will also provide further guidance on implementation and distribute this via NMVOs, who can then pass this to the End-User software providers. Ultimately it is the end-user system providers, in most cases, that are required to resolve these issues. Further monitoring will be undertaken.

Timelines and further meetings

In EMVO's Key Player Meeting with the BluePrint providers on Tuesday 26th February, the following topics will be discussed, further clarified and updated. Timelines to provide fixes to these issues will be defined, which EMVO will then provide to OBPs:

- The availability of Pack Disclosure Reports.
- GTIN grouping
- Emulated market support for use in conjunction with the 2018 OBP interface schema. This issue currently effects only ITE and IQE.
- Verification status, Product and Batch status hierarchy issue.
- Missing call-backs for Product Pack Verification in emulated markets. This issue currently effects only IQE and ITE environments.
- Normalisation of the point at which a pack expires such that all markets expire the pack at midnight on the date stated on the pack (and in the data)

EVI and further guidance



Further to this Letter of Announcement, EMVO can re-state that the primary method of communication we will use to inform OBPs of Known Issues will be the [EVI \(European Medicines Verification System Information\)](#).

We strongly encourage all OBPs to subscribe to the EVI as the best means to receive immediate updates on all Known Issues in the EMVS.

EMVO can also provide information on two updates to the EVI:

- 1 – New categories have been added, alongside colour coding, to give clearer indications of when entries are planned, modified, ongoing or outdated.
- 2 – On the EVI page there is now a legend, providing definitions of key terms.

Furthermore, EMVO will develop new features to the EVI such as introducing one notification when multiple countries are affected by a single issue. In addition, we will be upgrading the performance of the EVI.

EMVO has also strongly encourage NMVOs to nominate their IT BluePrint provider as being responsible for adding entries to the EVI on their behalf. This will ensure that information is provided accurately and that it is added to the EVI as quickly as possible. We believe that this is of particular merit as it will ensure that the same information is communicated about an issue which effects several countries.

Also, EMVO has encourage all account holders to include pdf documents on the EVI; in order to provide as much detail as possible on all Known Issues.

Finally, EMVO would also like to strongly advise all OBPs to log tickets with the EMVO Helpdesk. Logging tickets allows us to track issues and to investigate issues as a priority when they effect OBPs. Tickets also allow us to see trends developing and help us to gain as much information as possible about Known Issues.

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

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EMVO Team

European Medicines Verification Organisation

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